

**Remarks**

The claims have now been limited to the subject matter of Example 2 which is directed to treating diaper rash and decubitus ulcers.

Diaper rash and decubitus ulcers are somewhat related but are distinguished from other diseases or injuries because they are primarily the result of inflammation involving urine and bacteria that result in rashes.

**The Rejection Under 35 USC 103**

Reconsideration is respectfully requested of the rejection of the claims as presently amended under 35 USC 103 (a) as being unpatentable over Lezdey '684 in view of Costanzo.

Lezdey relates to damages to the skin resulting from ultra violet radiation from the sun. The damages include wrinkles, dryness and eruptions such as keratoses. Irritation from urine or bacterial inflammation is not involved. Both diaper rash and decubitus ulcers have a common cause, namely irritations resulting from urine pH and bacterial inflammation. Bacterial inflammation is not a mast cell disease initially. In bacterial inflammation complements C3a and C5a are involved which release TNF- $\alpha$ . TNF- $\alpha$  cause the release of inflammatory mediators.

Consequently, one skilled in the art would not consider there to be any relationship between sun damaged skin and diaper rash and decubitus ulcers. Therefore, Lezdey is silent with regard to the use of a cromolyn compound to treat diaper rash or

decubitus ulcers which are caused by irritations resulting from urine and bacterial inflammation.

Costanzo adds nothing to the teachings of Lezdey which would lead one in the art to the presently claimed invention.

Costanzo relates to treatment of immunomediated diseases, particularly with the respiratory tract and to skin depigmentation. None of these disorders would teach treatment of diaper rash or decubitus ulcers. Costanzo would not lead one in the art to treat a condition resulting from urine or bacterial inflammation. Decubitus ulcers are also a result of sweat and lack of aeration which also leads to bacterial infiltration.

Lezdey and Costanzo would not lead one in the art to treatment of skin eruptions which are due to bacterial inflammation.

Applicant has narrowed the invention to exclude skin eruptions in which mast cells are involved that result from an increase in IgE or sun damage.

#### **The Rejection Under 35 USC 112, 1<sup>st</sup> Paragraph**

The rejection of the claims as now presented as being unpatentable under 35 USC 112, 1<sup>st</sup> paragraph is not understood since by the nature of the invention, which is topical application, and knowledge of cromolyn being a PAR-2 inhibitor one can easily practice the invention.

The examples relate to topical compositions. Any layman can practice the invention. There is nothing complex to treating diaper rash. Mothers throughout the world treat diaper rash. Mothers can also predict the occurrence of diaper rash from the state of a diaper. In re Wands is not applicable to the present invention otherwise for use of the invention mothers would all have to be nuclear scientists. The decision in Fyr-Fyster Co. v International Chemical Extinguisher Corp., 122 USPQ 590, CA5 1959 which held "The theory is immaterial if the patent actually works as a new and useful device or method or improvement."

In the eight factors in In re Wands, it is clear that applicant has met the criteria by a reading of the claims together with the specification since this is not a complex case.

The applicant has now narrowed the claims to avoid the cited art and to relate to a method which can be easily practiced without any undue experimentation.

Reconsideration and favorable action are earnestly solicited.

Respectfully submitted,



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